

K991172

MAY 17 1999

510(k) Summary

Trade Name: Ionosit Bond

Sponsor: DMG Chemisch-Pharmazeutische Fabrik GmbH
Elbgastrasse 248
22547 Hamburg, Germany
Registration No. 8010567

Device Generic Name: Dental cement

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Predicate Device:

The proposed DMG Ionosit Bond material is substantially equivalent to the Vitrebond material marketed by 3M Dental Products, which was cleared for marketing by FDA in K962065 and K882821.

Product Description:

Ionosit Bond is a light-cure, glass ionomer liner/base material which is supplied in the form of a powder and liquid that are mixed prior to use. The liquid component contains a light sensitive polymerizable acid; the powder contains a fluoride-releasing special reactive glass.

Indications for Use:

Ionosit Bond is indicated for use in lining and basing applications under composite, amalgam, ceramic and metal restorations.

Safety and Performance:

Substantial equivalence for this device was based solely on design and technical specifications; no performance or safety data was included in this premarket notification. The materials, performance specifications and essential design characteristics of the Ionosit Bond material are equivalent to those of the predicate device. The proposed Ionosit Bond material complies with FDA's Guidance for Dental Cements as well as ISO 9917-Part 2 (dental water-based cements).

Conclusion:

Based on the indications for use, technological characteristics, and comparison to the predicate device, the Ionosit Bond material has been shown to be safe and effective for its intended use.

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(5) Technological characteristic of the gloves.

a. Dimensions

Sizes	XS	S	M	L	XL
Length	240 mm	240 mm	240 mm	240 mm	240 mm
Width	80 < mm	80±10 mm	95±10 mm	111±10 mm	>111mm

Thickness

1. Cuff (min)	0.10 mm	0.10 mm	0.10 mm	0.10 mm	0.10 mm
2. Palm (min)	0.10 mm	0.10 mm	0.10 mm	0.10 mm	0.10 mm
3. Finger Tip (min)	0.10 mm	0.10 mm	0.10 mm	0.10 mm	0.10 mm

b. Physical Properties

	Before aging	After aging at 70°C 168 hrs.
Tensile Strength :	21 Mpa	16 Mpa
Ultimate Elongation :	700 % (min.)	600 % (min.)

(6) Performance data is the same as mentioned immediately above.

(7) Clinical data is not needed for gloves or for most devices cleared by the 510 (K) process.

(8) Non-clinical data

We certify that these gloves meet ASTM D 3578 Standard.

Meets FDA pinhole requirement.

Meets labeling claim.